IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., WARNER-LAMBERT COMPANY LLC, PF PRISM C.V., PFIZER MANUFACTURING HOLDINGS LLC and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-759-CFC
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICALS INDUSTRIES, LTD.,	)	
Defendants.	)	

TEVA PHARMACEUTICALS USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD.'S ANSWER TO COMPLAINT

Defendants Teva Pharmaceuticals USA, Inc., ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (together as "Teva") hereby answer and assert the following defenses to the Complaint brought by Plaintiffs Pfizer Inc., Warner-Lambert Company LLC, PF Prism C.V., Pfizer Manufacturing Holdings LLC and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. (collectively "Pfizer" or "Plaintiffs").

With respect to the allegations made in the Complaint, Teva states as follows:

1. Teva admits that this purports to be an action for patent infringement of U.S. Patent Nos. 6,936,612 ("the '612 patent"); 7,208,489 ("the '489 patent"); 7,456,168 ("the '168 patent") (collectively, "the patents-in-suit") under the patent laws of the United States, Title 35, United States Code. Teva further admits that the Complaint purports to relate to Teva's filing of Abbreviated New Drug Application ("ANDA") No. 213088 with the United States Food and

Drug Administration ("FDA") for a generic version of IBRANCE® (palbociclib) capsules, 75 mg, 100 mg, and 125 mg. Teva denies any remaining allegations of paragraph 1.

2. Teva USA admits that it notified Pfizer by letter dated March 21, 2019 ("Teva's Notice Letter") that is had submitted ANDA No. 213088 to FDA for a generic version of IBRANCE® (palbociclib) capsules, 75 mg, 100 mg, and 125 mg. Teva denies any remaining allegations of paragraph 2.

PARTIES

3. Teva admits that Pfizer Inc. is the holder of New Drug Application ("NDA") No. 207103 for the manufacture and sale of palbociclib tablets, 75 mg, 100 mg, and 125 mg, which has been approved by the FDA. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' remaining allegations and therefore denies them.

4. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

5. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

6. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

7. Teva admits that Teva Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva, 49131, Israel. Teva further admits that Teva Ltd. is in the business, of among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Teva Pharmaceuticals, USA, Inc. Teva denies any remaining allegations in paragraph 7.

8. Teva admits that Teva USA is a corporation organized and existing under the laws of the State of Delaware, having places of business at 400 Interpace Parkway, Parsippany, NJ 07054 and1090 Horsham Road, North Wales, Pennsylvania 19454. Teva further admits that Teva USA is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market. Teva denies any remaining allegations in paragraph 8.

9. Teva admits that Teva USA is an indirect, wholly-owned subsidiary of Teva Ltd. Teva denies any remaining allegations in paragraph 9.

10. Teva USA admits that Teva USA prepared and submitted ANDA No. 213088. Teva denies the remaining allegations in paragraph 10.

11. Teva admits that Teva USA is an indirect, wholly-owned subsidiary of Teva Ltd. Teva denies the remaining allegations in paragraph 11.

12. Denied.

JURISDICTION AND VENUE

13. Paragraph 13 contains conclusions of law for which no response is required. To the extent that a response is required, and for the purposes of this case only, Teva does not contest subject matter jurisdiction in this matter.

14. Teva admits that Teva Ltd. is in the business of manufacturing and selling generic pharmaceutical products. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

15. Teva USA admits that it is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware and has appointed a registered agent for service of process in Delaware. Teva USA admits that it is in the business of

manufacturing and selling pharmaceutical drug products, including generic drug products in the United States. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them. For purposes of this case only, Teva USA does not contest personal jurisdiction over Teva USA.

16. Teva USA admits that it has previously engaged in patent litigation rising from the process contemplated by the Hatch-Waxman Act. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

17. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them. Teva further admits that it sent a Notice Letter to Pfizer, Inc. and further states that the Notice Letter is a document that speaks for itself. The remainder of this paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

18. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them. Teva further admits that it sent a Notice Letter to Pfizer, Inc. The remainder of this paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

19. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them. Teva USA further admits that it is in the business of manufacturing and selling pharmaceutical drug products, including generic drug products in the United States, including Delaware. The remainder of this paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

20. Teva USA admits that it is in the business of manufacturing and selling pharmaceutical drug products, including generic drug products in the United States, including

Delaware. The remainder of this paragraph contains his paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

21. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

22. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them. For purposes of this case only, Teva USA does not contest venue in this Court.

COUNT I-INFRINGEMENT OF THE '612 PATENT

23. Teva incorporates by reference its responses to Paragraphs 1-22 as if fully set forth herein.

24. Teva admits that the '612 patent lists on its face Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou as inventors. Teva lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 24 and therefore denies them.

25. Teva admits that the '612 patent is titled "2-(Pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones". Teva denies the remainder of this paragraph.

26. Teva admits that Pfizer is listed as the assignee on the face of the '612 patent. Teva lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 26 and therefore denies them.

27. Teva answers that the '612 patent is a document that speaks for itself. To the extent not expressly admitted, Teva denies the allegations of paragraph 27.

28. Teva answers that the '612 patent is a document that speaks for itself. To the extent not expressly admitted, Teva denies the allegations of paragraph 28.

29. Upon information and belief, Teva admits that the '612 patent has been listed in connection with IBRANCE in the FDA's Orange Book. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

30. Teva admits that it sent Pfizer a letter notifying them of Teva's submission of ANDA No. 213088 to the FDA. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

31. Teva admits that its letter notified Pfizer that it submitted ANDA No. 213088 to FDA and that ANDA No. 213088 contained a certification under 21 U.S.C. §355 (j)(2)(B)(iv), with respect to the '612 patent. Teva further admits that its ANDA contained certifications under 21 U.S.C. §355 (j)(2)(A)(vii)(IV) asserting that the '612 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA product. Teva denies any remaining allegations in paragraph 31.

32. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '612 PATENT

45. Teva incorporates by reference its responses to Paragraphs 1-44 as if fully set forth herein.

46. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

47. Teva answers that the '612 patent is a document that speaks for itself. To the extent not expressly admitted, Teva denies the allegations of paragraph 47.

48. Teva answers that the '612 patent is a document that speaks for itself. To the extent not expressly admitted, Teva denies the allegations of paragraph 48.

49. Teva admits that it sent Pfizer a letter notifying them of Teva's submission of ANDA No. 213088 to the FDA. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

50. Teva admits that its letter notified Pfizer that it submitted ANDA No. 213088 to FDA and that ANDA No. 213088 contained a certification under 21 U.S.C. §355 (j)(2)(B)(iv), with respect to the '612 patent. Teva further admits that its ANDA contained certifications under 21 U.S.C. §355 (j)(2)(A)(vii)(IV) asserting that the '612 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA product. Teva denies any remaining allegations in paragraph 50.

51. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

COUNT III –INFRINGEMENTOF THE ‘489 PATENT

63. Teva incorporates by reference its responses to Paragraphs 1-62 as if fully set forth herein.

64. Teva admits that the ‘489 patent lists on its face Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou as inventors. Teva lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 64 and therefore denies them.

65. Teva admits that the ‘489 patent is titled “2-(Pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones”. Teva denies the remainder of the allegations in this paragraph.

66. Teva admits that Pfizer is listed as the assignee on the face of the ‘489 patent. Teva lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 66 and therefore denies them.

67. Teva answers that the '489 patent is a document that speaks for itself. To the extent not expressly admitted, Teva denies the allegations of paragraph 67.

68. Upon information and belief, Teva admits that the '489 patent has been listed in connection with IBRANCE in the FDA's Orange Book. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

69. Teva admits that it sent Pfizer a letter notifying them of Teva's submission of ANDA No. 213088 to the FDA. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

70. Teva admits that its letter notified Pfizer that it submitted ANDA No. 213088 to FDA and that ANDA No. 213088 contained a certification under 21 U.S.C. §355 (j)(2)(B)(iv), with respect to the '489 patent. Teva further admits that its ANDA contained certifications under 21 U.S.C. §355 (j)(2)(A)(vii)(IV) asserting that the '489 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA product. Teva denies any remaining allegations in paragraph 70.

71. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '489 PATENT

84. Teva incorporates by reference its responses to Paragraphs 1-83 as if fully set forth herein.

85. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

86. Teva answers that the '489 patent is a document that speaks for itself. To the extent not expressly admitted, Teva denies the allegations of paragraph 86.

87. Teva admits that it sent Pfizer a letter notifying them of Teva's submission of ANDA No. 213088 to the FDA. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

88. Teva admits that its letter notified Pfizer that it submitted ANDA No. 213088 to FDA and that ANDA No. 213088 contained a certification under 21 U.S.C. §355 (j)(2)(B)(iv), with respect to the '489 patent. Teva further admits that its ANDA contained certifications under 21 U.S.C. §355 (j)(2)(A)(vii)(IV) asserting that the '489 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA product. Teva denies any remaining allegations in paragraph 88.

89. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

90. Denied.

91. Denied.

92. Denied.

93. Denied.

94. Denied.

95. Denied.

96. Denied.

97. Denied.

98. Denied.

99. Denied.

100. Denied.

101. Denied.

COUNT V –INFRINGEMENTOF THE ‘168 PATENT

102. Teva incorporates by reference its responses to Paragraphs 1-101 as if fully set forth herein.

103. Teva admits that the ‘168 patent lists on its face Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou as inventors. Teva lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 103 and therefore denies them.

104. Teva admits that the ‘168 patent is titled “2-(Pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones”. Teva denies the remainder of the allegations in paragraph 104.

105. Teva admits that Pfizer is listed as the assignee on the face of the '168 patent. Teva lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 105 and therefore denies them.

106. Teva answers that the '168 patent is a document that speaks for itself. To the extent not expressly admitted, Teva denies the allegations of paragraph 106.

107. Upon information and belief, Teva admits that the '168 patent has been listed in connection with IBRANCE in the FDA's Orange Book. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

108. Teva admits that it sent Pfizer a letter notifying them of Teva's submission of ANDA No. 213088 to the FDA. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

109. Teva admits that its letter notified Pfizer that it submitted ANDA No. 213088 to FDA and that ANDA No. 213088 contained a certification under 21 U.S.C. §355 (j)(2)(B)(iv), with respect to the '168 patent. Teva further admits that its ANDA contained certifications under 21 U.S.C. §355 (j)(2)(A)(vii)(IV) asserting that the '489 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA product. Teva denies any remaining allegations in paragraph 109.

110. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

111. Denied.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. Denied.

117. Denied.

118. Denied.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '168 PATENT

123. Teva incorporates by reference its responses to Paragraphs 1-122 as if fully set forth herein.

124. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

125. Teva answers that the '168 patent is a document that speaks for itself. To the extent not expressly admitted, Teva denies the allegations of paragraph 125.

126. Teva admits that it sent Pfizer a letter notifying them of Teva's submission of ANDA No. 213088 to the FDA. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

127. Teva admits that its letter notified Pfizer that it submitted ANDA No. 213088 to FDA and that ANDA No. 213088 contained a certification under 21 U.S.C. §355 (j)(2)(B)(iv), with respect to the '489 patent. Teva further admits that its ANDA contained certifications under 21 U.S.C. §355 (j)(2)(A)(vii)(IV) asserting that the '489 patent is invalid, unenforceable, and/or

will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA product. Teva denies any remaining allegations in paragraph 127.

128. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them.

129. Denied.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

135. Denied.

136. Denied.

137. Denied.

138. Denied.

139. Denied.

140. Denied.

PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint is a prayer for relief and does not require a response. To the extent that any response is required, Teva denies that Plaintiffs are entitled to any relief for the allegations and claims made in the Complaint, including the relief requested in subsections (a)-(g). Each averment and/or allegation contained in Plaintiffs' Complaint that is not specifically admitted herein is hereby denied.

AFFIRMATIVE DEFENSES

FIRST DEFENSE
(Failure to State a Claim)

Plaintiffs fail to state a claim upon which relief can be granted.

SECOND DEFENSE
(Non-infringement)

Teva has not and will not infringe directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner any valid and enforceable claim of the '612, '489 and '168 patents.

THIRD DEFENSE
(Invalidity)

The claims of the '612, '489 and '168 patents are invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including without limitation 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or obviousness-type double patenting.

FOURTH DEFENSE
(Additional Defenses)

Teva reserves the right to add or amend this list of Affirmative Defenses with additional defenses that discovery may yield.

/s/ Karen E. Keller
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